

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

PHILIP MORRIS USA INC. et al.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION et al.,

Defendants.

Case No. 1:15-cv-01590-APM

NOTICE OF INFORMATIONAL REQUEST

Plaintiffs respectfully request that the Court ascertain certain information that may be relevant to the potential applicability of 28 U.S.C. § 455 in this case. Based on publicly available information, Plaintiffs understand that Your Honor was, until his recent accession to the bench, a partner in the Washington, D.C. office of Zuckerman Spaeder LLP. The Campaign for Tobacco-Free Kids (“CTFK”), an anti-tobacco organization, has been a longstanding client of Zuckerman Spaeder. Indeed, the firm has long advocated on behalf of anti-tobacco organizations, including by writing numerous *amicus* briefs against tobacco companies for CTFK, the American Cancer Society Cancer Action Network, the American Heart Association, and the American Lung Association.

Much of Zuckerman Spaeder’s work on tobacco issues has focused on statutory issues under the Family Smoking Prevention and Tobacco Control Act (“TCA”). The firm’s website notes its involvement on behalf of a “leading public health group in negotiations . . . culminating

in the enactment of the [TCA].”¹ Lobbying reports indicate that this “public health group” was CTFK.² The firm’s website states further that Zuckerman Spaeder still “advises this group regarding FDA implementation of the new law.”³ A principal Zuckerman Spaeder lawyer representing CTFK was William Schultz, a former Deputy Commissioner of FDA. (Mr. Schultz left the firm in 2011 to become Deputy General Counsel and then General Counsel of HHS.) Another principal lawyer for CTFK lists “administrative practice before the Food and Drug Administration,” as a key focus of his practice. He in fact has delivered at least one presentation on the TCA’s substantial equivalence process at issue in this case. *See* Carlos T. Angulo, Zuckerman Spaeder LLP, *Tobacco Product Standards: A Public Health Perspective* (Oct. 21, 2014), <http://goo.gl/G1VTnF>. A third Zuckerman Spaeder lawyer for CTFK likewise cites his expertise on food and drug law and also notes his experience as a trial attorney in the Justice Department lawsuit against the tobacco industry.

This case involves a challenge by Plaintiffs to actions taken by the FDA under the TCA. Plaintiffs challenge on numerous statutory and constitutional grounds a putative “Guidance” issued by the FDA on September 8, 2015. The FDA first published the “Guidance” as a draft in September 2011 and invited comments. Compl. ¶ 39. CFTK, the American Cancer Society Cancer Action Network, the American Heart Association, and the American Lung Association—all apparently current or former clients of Zuckerman Spaeder—submitted comments to the FDA

¹ Zuckerman Spaeder, Our Practice, Food & Drug, <http://www.zuckerman.com/practices-Food-and-Drug-FDA.html>.

² OpenSecrets.org, Annual Lobbying by National Center for Tobacco-Free Kids, 2008, <http://www.opensecrets.org/lobby/clientsum.php?id=D000046146&year=2008> (also providing access to figures for other relevant years, 2002 to 2007). The National Center for Tobacco-Free Kids appears to be the same entity as CTFK. *See* Robert Wood Johnson Foundation, *The Campaign for Tobacco-Free Kids* (2009), <http://www.rwjf.org/en/library/research/2009/03/the-campaign-for-tobacco-free-kids.html>.

³ Zuckerman Spaeder, Our Practice, Food & Drug, <http://www.zuckerman.com/practices-Food-and-Drug-FDA.html>.

in November 2011, addressing many issues raised in Plaintiffs' Complaint here. *See* Comments of CTFK et al., Dkt. No. FDA-2011-D-0147, <http://goo.gl/42cJ5n>. Plaintiff Philip Morris USA Inc. also submitted comments. *See* Compl. ¶ 39. Fifteen months later, CTFK and the other anti-tobacco groups filed an 82-page response to those comments, to which Plaintiff Philip Morris USA Inc. responded in June 2013.⁴ The Final Guidance issued by FDA in September 2015 tracked arguments presented in CTFK's response.

CTFK's comments are on the organizations' letterhead and do not indicate who wrote or participated in drafting them. But given the longstanding attorney-client relationship between Zuckerman Spaeder and CTFK, the firm's work for CTFK on issues relating to FDA regulation of tobacco products, and the firm's involvement in anti-tobacco litigation generally, there appears to be a reasonable prospect that, while Your Honor was a partner at Zuckerman Spaeder, lawyers in the firm participated in drafting CTFK's multiple rounds of comments on the various iterations of the FDA Guidance that is the subject of this lawsuit.

In light of the foregoing we respectfully request that the Court take appropriate steps to ascertain whether any Zuckerman Spaeder lawyer was involved in advising, counseling or representing CTFK or any other anti-tobacco organization in connection with the Guidance while Your Honor was a partner at the firm. We submit that this information is relevant to the potential applicability in this case of 28 U.S.C. § 455.

⁴ CTFK also submitted comments in early April 2015 concerning FDA's March 4, 2015 "Final Guidance," and later in April addressing FDA's interim enforcement policy regarding the Guidance. The organization filed still more comments on July 22, 2015, after FDA withdrew its March 4 "Final Guidance" for revision following Plaintiffs' initial lawsuit challenging it. CTFK's July 2015 comments again focused on core issues raised in the Complaint here. *See* Dkt. No. FDA-2011-D-0147, <http://goo.gl/ji0zmy>; Dkt. No. FDA-2010-D-0635, <http://goo.gl/svIsHC>; Dkt. No. FDA-2013-D-1600-0005, <http://goo.gl/f9ZTbK>; *see also* American Lung Association, <http://www.lung.org/assets/documents/advocacy-archive/letter-to-ctp-re-se-guidance.pdf>.

Dated: October 21, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 21, 2015, I caused to be served a true and correct copy of the foregoing Notice of Informational Request to be sent via email and first class mail, postage prepaid, to counsel for Defendants:

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